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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,276	09/07/2000	Dominique P. Bridon	REDC-2111 USA	9972

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EXAMINER
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SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/02/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant N .

09/657,276

Applicant(s)

BRIDON ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9, 11-17 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9, 11-17 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Amendment***

1. This Office Action is in response to Paper #17, filed 24 December 2002. Applicant's amendment of claims 7 and 15 is acknowledged. Claims 1-6, 10 and 18-20 have been previously canceled. Claims 7-9, 11-17 and 21-25 are under pending.

2. Applicant's request for an Interview in paper filed 4 April 2003 is acknowledged. Applicant was called 24 June 2003 and advised that prior response to this office action, should it be necessary, applicant should request and/or contact the examiner to arrange a date and time for an interview.

### ***Withdrawal of Objections and Rejections***

3. The objections and/or rejections not explicitly restated or stated below are withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection of claims 15 under 35 U.S.C. 112, second paragraph, is MAINTAINED for the reasons set forth in the Office Action mailed 4/30/02, Paper No. 12, and those found below.

5. The rejection of the phrases "therapeutically active region" and "less therapeutically active region" is maintained. Additionally, applicant has amended the claims to further qualify "therapeutically active region" in the claim, specifically by indicating that the "therapeutically

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active region” are identified using structure activity analysis. This argument is not persuasive, as these terms are relative. What is considered active or less active in one case, may not be so in another case. For example, one region may be more active for one activity or function and at the same time is less active for another. The terms "more" and "less" are relative term are only made definite when referring to a single concrete point, not to a broad general concept. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 11-17 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pouletty *et al.* (US 6,103,223) in view of Oppenheim *et al.* (5,837,247).

Pouletty *et al.* teach a method for protecting a therapeutic peptide that is sensitive to peptidase degradation in vivo. The method involves preparing a composition in which first and second components are provided. The first component is administered to a mammalian host into blood for covalent bonding to a second blood component, where the components have an extended lifetime in the blood stream. The first component comprises an active functionality and an agent of interest or a first binding entity. A second component may be subsequently administered to the patient, which comprises a second binding entity, complementary to the first

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binding entity and an agent of interest. By virtue of binding to long-lived blood components, the half-life of the agent of interest is greatly extended in vivo. The first compound will comprise the active functionality, a linking group, and the agent of interest or first binding entity.

The functionalities which are available on proteins are primarily amino groups, carboxyl groups and thiol groups. While any of these may be used as the target of the reactive functionality, for the most part, bonds to amino groups will be employed, particularly formation of amide bonds. To form amide bonds, one may use a wide variety of active carboxyl groups, particularly esters, where the hydroxyl moiety is physiologically acceptable at the levels required. While a number of different hydroxyl groups may be employed, the most convenient will be N-hydroxysuccinimide, and N-hydroxy sulfosuccinimide. As the first component may be active proteins, regions of differing therapeutic activity is inherent. Serum albumin is disclosed as a long-lived blood associated second component. The anchor is disclosed as comprising N-hydroxy succinimide ester (regarding claim 11). The conjugate may be administered in vivo or ex vivo.

Pouletty *et al.* disclosed is a method of analyzing the peptide-blood component for increased half-life. Pouletty *et al.* does not expressly teach the added step in analyzing the peptide blood component for resistance to peptidase degradation.

Brenton *et al.* teach that the conjugation of a peptide to albumin protects the conjugate from peptidase degradation that results in the increased half-life.

Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to perform the analyzing step of the peptide blood component for resistance to peptidase degradation. Analyzing the peptide blood component for resistance to peptidase

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degradation is an alternative method to determine the increased half-life of an albumin conjugate, and a person of ordinary skill in the art would have been motivated to perform the analysis in order to determine if the conjugate resulted in a composition that had an increase half-life over the active peptide alone. The person of ordinary skill in the art would have expected success in finding a compound of increased half-life having analysis the conjugate for resistance to peptidase degradation. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Conclusion***

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
June 30, 2003

SKS

*Christopher S.F. Low*

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